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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/876,437	06/16/1997	MARIANTHI GIAKOUMAKIS		5017

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EXAMINER
CAMPEN, KELLY SCAGGS

ART UNIT	PAPER NUMBER
3624	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/876,437	GIAKOUMAKIS, MARIANTHI	
	Examiner	Art Unit	
	Kelly Campen	3624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 25-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 25-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/7/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

References in the search report submitted by the applicant for GB Patent application No. GB 9721337.5, and references cited in the European Patent EP 1063961 B1, as well as any other references applicant may be aware of in applicant's other foreign filings (Canadian 2213646; AU2004201250; NZ504388; GB2318054; DE69724840T; AT249199T). In addition,

Examiner requests a full and complete copy of each published application/patent including the full search report with all referenced/applied prior art references AND ALL LISTED PROPERLY ON THE IDS.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain

an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. **A complete reply to the enclosed Office action must include a complete reply to this requirement.** The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Examiner continues to be unable to contact the web site for "South African Medicines Formulary; Vitamins." It is requested that applicant confirm that web site is still active and open.

35 USC § 112 and 35 USC § 101

Claims 25-31 are rejected under 35 U.S.C. 101 because the claimed invention, sustainable, non surgical breast enlargement through the continued application of cocoa butter and Vitamin E is not supported by either a credible asserted utility or a well established utility.

Applicant's assertion of specific credible utility is not considered credible. One of ordinary skill in the art would not find applicant's assertion of utility credible because applicant has not offered any statistically significant evidence to prove such.

Claims 25-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention and would not find applicant's assertion of utility credible because applicant has not offered any statistically significant evidence to prove such as stated previously.

In addition, see MPEP 2107.03,

> " affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible."

As such, Applicant has relied upon the Cayce reference to teach the use of cocoa butter to increase breast size. The only assertion is the closest prior art that contradict Applicant's allegation. See Cayce, page 285, line 8, "To Reduce Bust" continuing in lines 9-22 describing the use of cocoa butter massaged into the breast to reduce the size of the bust.

Therefore, the disclosed method of breast enlargement would not be accepted as obviously valid by one of ordinary skill in the art. In addition, see the cited prior art (Van Dellen, Martineau 6/1903 and 2/1904) not relied upon for further examples of not obviously valid by one of ordinary skill in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 31are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 50 grams of cocoa butter at age 30, does not reasonably provide enablement for 7 grams of cocoa butter at age 35. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification clearly states that it takes more cocoa butter and longer to absorb the cocoa butter at an older age and at 30 it requires 50 grams. It goes on to indicate for an example that while it took 11 consecutive hours to absorb 50 grams of cocoa butter at age 30, at age 35 it took over 4 hours just to absorb 7 grams. See page 5, paragraph 2 of the instant specification:

> [The amount of cocoa butter used is directly proportional to the augmentation of the breast's size. It has been found that approximately 50g of cocoa butter per breast enlarges each breast from an A size bra cup to a B size bra cup. For such an amount, the application time for the applicant, at a younger age of approximately 30 years old and under, was approximately 11 consecutive hours of application of the cocoa butter...
>
> However, at an older age... the applicant had found that response time of the body to the application of cocoa butter took significantly longer for the breast to augment in size. At the age of 35 years, it would then take the applicant 4 to 6 hours to absorb about 7g of cocoa butter.]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell (Chicago Daily Tribune, 1911). Russell discloses a method of enlarging a breast with cocoa butter but does not disclose the use of vitamin E. Vitamin E is commonly used to treat the skin, it is readily found in any body lotion for the skin, including the breast. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Vitamin E and cocoa butter to treat the breast as both are well known for treating dry skin, including treating the nipple and breast when nursing and for treating the skin to prevent or lessen the effects of stretch marks.

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martineau (Chicago Daily Tribune, 1903). Martineau discloses a method of enlarging a breast with cocoa butter but does not disclose the use of vitamin E. Vitamin E is commonly used to treat the skin, it is readily found in any body lotion for the skin, including the breast. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Vitamin E and cocoa butter to treat the breast as both are well known for treating dry skin, including treating the nipple and breast when nursing and for treating the skin to prevent or lessen the effects of stretch marks.

Response to Arguments

Applicant's arguments with respect to claims 16-25 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's reference to the "third office action", the third office action was dated 7/21/1998. For Examination purposes, Examiner understands the third office action to refer to the prior office action dated 8/2/2004.

With regards to applicant's attempt to respond to the 105 request, Examiner accepts that this was a *bona fide* attempt at a response but directs applicant to the new 105 request with emphasis added.

While the Cayce reference in longer being applied, it is clear that Cayce does disclose a method of breast enhancement. In addition, since the applicant did not specifically respond to the use of Vitamin E as obvious, it is now considered admitted prior art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Musher (US4454159) discloses dermatological preparations of Vitamin E and cocoa butter. Linares (US005770183A) discloses skin compositions of Vitamin E and cocoa butter with their uses. Crandall (US005945409A, US006316428B1) discloses a topical moisturizing composition and its use with cocoa butter and Vitamin E. Durr et al. (US005997889A) disclose had and body creme for the treatment of skin ailments with cocoa butter and Vitamin E.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly Campen whose telephone number is (571) 272-6740. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on (571) 272-6747. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kelly S. Campen

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